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AWARD NUMBER: W81XWH-14-1-0410

TITLE: "Imaging Depression in Adults with ASD"

PRINCIPAL INVESTIGATOR: Kenneth Gadow, Ph.D.

CONTRACTING ORGANIZATION: New York, State University of, Stony Brook
 Stony Brook, NY 11794-3362

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14. ABSTRACT Aim A: To determine if the immunologic bias in autism spectrum disorder (ASD) confers greater risk for co-occurring depression than severity of ASD. If depression severity is associated with increased cytokine levels (reported in non-ASD adults), this would support the notion that depression is a valid clinical syndrome within the ASD clinical phenotype, but not necessarily the same disorder as in neurotypical populations. Aim B: To determine if depression symptoms are associated with clinical features similar to previous research about depression in neurotypical adults {e.g., brain activation in response to social stress and correlation with cytokine levels and depression severity). If findings are consistent, this would support the notion that depression may be a "true" co-morbidity. Method: Participants will be men {N=SO) 18-45 years old with IQ BO and ASD diagnosis, no previous head trauma, no seizure or autoimmune disorder, and no current immunologic medication. Participants will be complete diagnostic and psychosocial assessments and a blood draw. A significant other will also complete emotion symptom measures. Individuals with low and high depression symptoms will be selected for participation the imaging phase. Functional scans will be acquired during a social acceptance/rejection task (Cyberball), followed by an exploratory hedonic reward task, Monitory Incentive Delay. The research is in progress with no results to report to date.

1S. SUBJECT TERMS
AUTISM, BRAIN IMAGING, DEPRESSION, SOCIAL REJECTION

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
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1. INTRODUCTION:

Background: The main reason for conducting this study is to use brain imagining technology to better understand how the immune system and environmental stressors contribute to emotional symptoms in higher functioning adults with ASD. Hypotheses: (1) Severity of ASD and emotional symptoms in participants with ASD will each be associated with an elevated systemic inflammatory state indicated by increased peripheral levels of inflammatory cytokines (e.g., IL-6, TNF-a). (2) Participants undergoing fMRI will show (a) greater dorsal anterior cingulate cortex (dACC) activation following social rejection than social acceptance, and this will be (b) differentially greater in participants with elevated versus low emotion symptoms. (3) Higher levels of inflammatory cytokines will predict higher dACC activation following social rejection versus inclusion, and this will be moderated by emotional status (i.e., relation will be stronger among those in the high versus low emotion symptom group). Exploratory hypotheses will address parallel relations using an fMRI reward anticipation task. Method: Phase 1 participants will be men (N=50) between 18 and 45 years of age with a full scale IQ≥ 80 and diagnosis of ASD, and not be receiving psychotropic medication. ASD participants will be administered ASD and emotional assessment measures and complete a blood draw. A significant other will also complete emotion symptom measures. Individuals with low and high emotion symptoms will be selected for participation the Phase 2 imaging study. Functional scans will be acquired during a social acceptance/rejection task (Cyberball), which will be followed by an exploratory hedonic reward task, Monitory Incentive Delay.

2. KEYWORDS:

autism, brain imaging, depression, social rejection

3. ACCOMPLISHMENTS:

What were the major goals of the project for Year 1?

In this report, we detail the accomplishments met on the study to date, and propose a revised SOW (Appendix A). This revised SOW is mapped on to a project timeline reflective of a one-year no-cost extension to this project, which may be requested at the conclusion of the next reporting period. All objectives enumerated in the revised SOW are consistent with those in the existing approved SOW. Appendices have been included supporting this account and confidently supporting the successful completion of this project (see Appendices B, C).

YEAR 1: Revised SOW

Aim #1: Obtain Institution Review Board (IRB) approval for DOD application
    1a. Task: Obtain IRB approval Responsible personnel: Dr. Gadow Milestone: IRB approval secured
    SOW Timeline: Prior to award Week 0 (9/30/2014)
    Actual Completion Date: 4/17/2014

    1b. Task: Submit IRB DOD amendment to existing IRB approval
    Responsible personnel: Dr. Gadow
    Milestone: Complete and submit IRB amendment
    SOW Timeline: Weeks 1-4 (10/7/2014 -10/28/2014)
    Actual Completion Date: 7/28/2014

    1c.Task: Obtain IRB amendment approval
    Responsible personnel: Dr. Gadow
    Milestone: Complete and submit revised IRB forms SOW Timeline: Weeks 4-6 (10/28/2014 - 11/11/2014) Actual Completion Date: 7/31/2014

Aim #2: Prepare for subject recruitment
    2. Task: Prepare subject recruitment materials Responsible personnel: Dr. Gadow, Coordinator
    Milestones: Solicitation lists, advertisements
    SOW Timeline: Weeks 6-11 (11/11/2014- 12/16/2014) Actual Completion Date: 8/1/2014; 2/23/2015

Aim # 3: Recruitment, data collection, and data processing for Phase 1
    3a. Task: Recruitment of first block of 28 Phase 1 participants Responsible personnel: Dr. Gadow,
    Coordinator Milestone: Initiate participant solicitation
    SOW Timeline: Weeks 12-52 (12/23/2014- 9/30/2015)
    % of Milestone Complete: 86% (Please see below for details and revised timeline)

    3b. Task: Collect psychosocial data
    Responsible personnel: Dr. Gadow, Dr. Lerner, Dr. Sprafkin, Coordinator Milestones: Administer
    diagnostic and psychosocial measures, collect blood samples SOW Timeline: Weeks 12-52
    (12/23/2014- 9/30/2015)·
    % of Milestone Complete: 0% (Please see below for details and revised timeline)

    3c. Task: Record and enter diagnostic and psychosocial data Responsible personnel: Dr. Gadow,
    Dr. Lerner, Coordinator Milestones: Score assessment measures and enter data for analyses SOW
    Timeline: Weeks 12-52 (12/23/2014- 9/30/2015)
    % of Milestone Complete: 0% (Please see below for details and revised timeline)

    3d. Task: Collecting, storing, and processing Phase 1 immunologic data
    Responsible personnel: Dr. Trujillo
    Milestones: Collect and properly store blood samples
    SOW Timeline: Weeks 12-52 (12/23/2014- 9/30/2015)
    % of Milestone Complete: 0% (Please see below for details and revised timeline)

Aim # 4: Recruitment, data collection, and data processing for Phase 2
    4a. Task: Recruitment of first block of 17 Phase 2 participants
    Responsible personnel: Dr. Gadow, Dr. Lerner, Dr. DeLorenzo, Coordinator
    Milestone: Initiate participant solicitation
    SOW Timeline: Weeks 12-52 (12/23/2014- 9/30/2015)
    % of Milestone Complete: 0% Please see below for details and revised timeline)

    4b. Task: Conduct fMRI
    Responsible personnel: Dr. Gadow, Dr. Lerner, Dr. DeLorenzo, Coordinator
    Milestone: Conduct fMRis
    SOW Timeline: Weeks 12-52 (12/23/2014- 9/30/2015)
    % of Milestone Complete: 0% (Please see below for details and revised timeline)

    4c. Task: Storing and processing Phase 2 fMRI data
    Responsible personnel: Dr. DeLorenzo
    Milestones: Storing and initial processing fMRI data Weeks 12-52
    SOW Timeline: Weeks 12-52 (12/23/2014- 9/30/2015)
    % of Milestone Complete: 0% (Please see below for details and revised timeline)

What was accomplished under these goals for Year 1?

Aim #1: Obtain Institution Review Board (IRB) approval for DOD application
    IRB approval at each step was secured well ahead of SOW timelines. Additionally, IRB renewal was
    required within this reporting period. Continuing Review materials were submitted to IRB on
    2/23/2015, and approved on 5/5/2015; approval of Continuing Review was then submitted to
    USAMRMC ORP HRPO on 5/8/2015, and was acknowledged on 5/11/2015.

Aim #2: Prepare for subject recruitment
    IRB-approved web postings and recruitment materials were disseminated upon amendment
    approval (i.e., 8/1/2014). A revised advertisement was submitted to IRB in Continuing Review
    (2/23/2015), which contains more information about the purpose and procedures of the study
    than original advertisement and updated telephone contact for the Coordinator. Upon IRB
    approval of the revised advertisement (5/5/2015), this new material was disseminated.
    While these dates note specifically the preparation of subject materials, distribution efforts have
    been ongoing since 8/1/2014. As indicated in the IRB application, the primary recruitment method

for this study is the distribution of approved recruitment materials via local clinical facilities, organizations, and individual providers who support this project, to target the ASD population, as opposed to disseminating recruitment materials to the public more broadly. Thus, our efforts on this task have focused on building and maintaining relationships with and providing recruitment materials to local clinical contacts that have a combined reach of 200+ adult HFASD males. See Aim 3 below for preliminary yield.

Aim# 3: Recruitment, data collection, and data processing for Phase 1
      3a.Milestones: Initiate participant solicitation
      3b. Milestones: Administer diagnostic and psychosocial measures, collect blood samples
      3c. Milestones: Score assessment measures and enter data for analyses
      3d. Milestone: Collect, store, and process Phase 1 blood samples

         Progress to Date: Recruitment efforts to date have yielded a pool of 24 prospective participants who have met preliminary screening criteria (e.g., existing diagnosis of HFASD, male) and have provided contact information, requesting to be contacted to enroll in the study. Additionally, PI Dr. Gadow, Co-I Dr. Lerner, and Coordinator have approval to hold informational tables advertising this study and other research participation opportunities of the PI Dr. Gadow and Co-I Dr. Lerner at two relevant local conferences: 1. Asperger Syndrome & High Functioning Autism Association's Fall Conference;10/24/2015; attendees include educators, clinicians and administrators who work with ASD, as well as individuals with ASD and parents of individuals with ASD.2. Meeting of the Minds Symposium on Autism Spectrum Disorders hosted by Stony Brook University Neurosciences Institute; 10/30/2015; open to all physicians, nurses, researchers, students and other healthcare professionals or caregivers with an interest in autism spectrum disorders, open to the public.

         No subject was consented or enrolled in the full. As described in greater detail in Section 5 of this report and the supporting Appendices, data collection for the imaging phase of the study was delayed due to difficulties with the scanner. In order to (a) ensure that diagnostic and psychosocial data and blood samples from Phase 1 are collected temporally close enough to imaging data in Phase 2 to be confidently incorporated in the planned statistical analyses, and (b) not unduly risk attrition between Phase 1 and 2, we chose to hold off on Phase 1 data collection until scanner issues were resolved and Phase 2 data collection is imminent.

Aim # 4: Recruitment, data collection, and data processing for Phase 2
      As described in greater detail in Section 5 of this report and the supporting Appendices, data collection for the imaging phase of the study were delayed due to difficulties with the scanner. Please see Appendix A: Revised SOW for the timeline to complete this Aim.

YEAR 2: Revised SOW

What were the major goals of the project for Year 2?

Aim # 3: Recruitment, data collection, and data processing for Phase 1
      3a.Task: Recruitment of first block of 10 Phase 1 participants
      Responsible personnel: Dr. Gadow, Coordinator
      Milestone: Continue participant solicitation
      Timeline: Weeks 1-34 (10/1/2015 – 6/1/2016)

      3b. Task: Collect psychosocial data
      Responsible personnel: Dr. Gadow, Coordinator
      Milestones: Administer diagnostic and psychosocial measures, collect blood samples
      Timeline: Weeks 34-52 (6/1/2016 – 9/30/2016)

      3c. Task: Record and enter diagnostic and psychosocial data
      Responsible personnel: Dr. Gadow, Coordinator
      Milestones: Score assessment measures and enter data for analyses
      Timeline: Weeks 34-52 (6/1/2016 – 9/30/2016)

      3d. Task: Collecting and storing Phase 1 immunologic data
      Responsible personnel: Dr. Gadow, Coordinator

Milestones: Collect and properly store blood samples
Timeline: Weeks 34-52 (6/1/2016 – 9/30/2016)

Aim # 4: Recruitment, data collection, and data processing for Phase 2
4a. Task: Recruitment of first block of 3 Phase 2 participants
Responsible personnel: Dr. Gadow, Dr. DeLorenzo, Coordinator
Milestone: Initiate participant solicitation
Timeline: Weeks 39-52 (7/1/2015 – 9/30/2016)

4b. Task: Conduct fMRI
Responsible personnel: Dr. Gadow, Dr. DeLorenzo, Coordinator
Milestone: Conduct fMRIs
Timeline: Weeks 39-52 (7/1/2015 – 9/30/2016)

4c. Task: Storing and processing Phase 2 fMRI data
Responsible personnel: Dr. DeLorenzo
Milestones and timeline: Storing and initial processing fMRI data Weeks 39-52 (7/1/2015 – 9/30/2016)

What was accomplished under these goals for Year 2?

Aim# 3: Recruitment, data collection, and data processing for Phase 1
3a. Milestones: Initiate participant solicitation
3b. Milestones: Administer diagnostic and psychosocial measures, collect blood samples
3c. Milestones: Score assessment measures and enter data for analyses
3d. Milestone: Collect, store, and process Phase 1 blood samples
            Progress to Date: Recruitment efforts to date have yielded a pool of 70 prospective participants to date who have met preliminary screening criteria (e.g., existing diagnosis of HFASD) and have provided contact information, requesting to be contacted to enroll in the study. Additionally, PI Dr. Gadow, Co-I Dr. Lerner, and Coordinator have approval to hold informational tables advertising this study and other research participation opportunities of the PI Dr. Gadow and Co-I Dr. Lerner at two relevant local conferences: 1. Asperger Syndrome & High Functioning Autism Association's Fall Conference; 10/15/2016; attendees include educators, clinicians and administrators who work with ASD, as well as individuals with ASD and parents of individuals with ASD.
            Five subjects have consented to and enrolled in Phase 1 of the study to date. As described in greater detail in Section 5 of this report and the supporting Appendices, data collection for the imaging phase of the study was previously delayed due to difficulties with the scanner. In order to (a) ensure that diagnostic and psychosocial data and blood samples from Phase 1 are collected temporally close enough to imaging data in Phase 2 to be confidently incorporated in the planned statistical analyses, and (b) not unduly risk attrition between Phase 1 and 2, we chose to hold off on Phase 1 data collection until scanner issues were resolved and Phase 2 data collection was imminent.

Aim # 4: Recruitment, data collection, and data processing for Phase 2

Two date one participant successfully completed the Phase 2 scan, and a second participant completed the scan 10/12/16. Please see Appendix A: Revised SOW for the timeline to complete this Aim.

What opportunities for training and professional development has the project provided?

• PI Dr. Gadow and Co-I Dr. Lerner have each mentored Coordinator Rebecca Weber one-on-one in data management and analytic techniques.
• Coordinator Rebecca Weber and Co-I Dr. Lerner's Clinical Psychology PhD students have participated in weekly training for the Structured Clinical Interview for DSM IV to be administered in Phase 1, for which weekly clinical supervision is ongoing (since 9/2014).
• Co-I Dr. Lerner's 2nd year Clinical Psychology PhD students have participated in ADOS-2 Introductory Clinical Training and ADOS-2 Advanced/Research Training by New York

Presbyterian Center for the Developing Brain (CADS), Weill Cornell Medical College, & Columbia University Medical Center (7/2014) and successfully undergone review to be certified (12/2014, 7/2015) as research-reliable examiners for this gold-standard ASD diagnostic assessment (Autism Diagnostic Observation Schedule, 2nd edition), to be administered in Phase 1.

- Likewise, Co-I Dr. Lerner's 1st year Clinical Psychology PhD has participated in ADOS-2 Introductory Clinical Training by New York University Child Study Center (8/2015) and ADOS-2 Advanced/Research Training by Weill Cornell Medical College & CADB (10/2015), and is currently completing steps toward reliability review.
- Co-I Dr. Lerner has trained Coordinator Rebecca Weber and his Clinical Psychology PhD students in administration of the Kaufman Brief Intelligence Test, 2nd edition, to be administered in Phase 1 (7/2014).
- Coordinator Rebecca Weber has completed training and certification in Phlebotomy for Research (Adults) at Stony Brook University Hospital, which consisted of 3 hours of classroom instruction (9/2014) and 20 hours of practicum with adult inpatients and outpatients under direct supervision of Stony Brook University Hospital Phlebotomy staff (11/2014). Coordinator will be responsible for Phase 1 blood draws.

How were the results disseminated to communities of interest?

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?

As detailed Appendix A: Revised SOW, the goals for the next reporting period revolve around data collection of more than 50°/o of the study sample for both Phase 1 and 2. The reasons for the revised timeline are enumerated elsewhere in this report. We are confident in the timelines for milestones outlined in the Revised SOW, as a solution to the cause of the delay has been reached. The scanner to be used for Phase 2 data collection is now operational and we have scanned two participants to date.

PI Dr. Gadow, his Coordinator and students will continue to seek out ASD community events/conferences for additional future large-scale recruitment opportunities to supplement interest generated by local clinical contacts as needed to maintain target enrollment rates.

PI Dr. Gadow and Co-I Dr. Lerner will oversee collection of diagnostic and psychosocial data by Coordinator and Clinical Psychology PhD students and will provide clinical guidance throughout the study on a subject-by-subject basis as needed to ensure high quality of diagnostic and psychosocial data. PI Dr. Gadow, Co-I Dr. DeLorenzo, and Co-I Dr. Lerner will oversee Phase 2 data collection, for which the Coordinator will be present for all subjects. All investigators have extensive experience in collecting, storing, and processing the type of data for which they are responsible on this project.

4. IMPACT:

What Was the impact on the development of the principal discipline(s) of the project?

Nothing to Report.

What Was the impact on other disciplines?

Nothing to Report.

What was the impact on technology transfer?

Nothing to Report.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change:

    Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them:

    Please see Appendix B for an account of the problems/delays faced with the SCAN Center as well as details on the course of action agreed upon by PI Dr. Gadow and Co-I Dr. Parsey to circumvent these problems and facilitate successful data collection for this project. Likewise, please see Appendix C for direct correspondence from SCAN Center Director Dr. Turhan Canli. In summary, Phase 2 data collection is currently utilizing the SBUH research-dedicated PET/MR (now fMRI-capable) scanner. This change has no impact on the expenditures of the grant (see Appendix B) nor the direction of the project; the only impact identified pertains to time, which is addressed in Appendix A.

Changes that had a significant impact on expenditures

    Nothing to Report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

    Nothing to Report.

6. PRODUCTS:

- Publications, conference papers, and presentations. Nothing to report.

- Journal publications. Nothing to Report.

- Books or other non-periodical, one-time publications. Nothing to Report.

- Other publications, conference papers, and presentations. Nothing to Report.

- Website(s) or other Internet site(s) Nothing to Report.

- Technologies or techniques Nothing to Report.

- Inventions, patent applications, and/or licenses Nothing to Report.

- Other Products Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

1. Name: Kenneth D. Gadow, PhD
   Contribution to Project: No change.

2. Name: Ramin Parsey, MD, PhD
   Contribution to Project: No change.

3. Name: Christine DeLorenzo, PhD
   Contribution to Project: No change.

4. Name: Matthew Lerner, PhD
   Contribution to Project: No change.

5. Name: Patricia Whitaker-Azmitia, PhD
   Contribution to Project: No change.

6. Name: Jie Yang, PhD
   Contribution to Project: No change.

7. Name: Project   Glenda Trujillo, PhD
   Role: Co-Investigator
   Person months worked: 0.02
   Contribution to Project: Dr. Trujillo made recommendations for the assays to be used for analysis of immunologic markers in Phase 1 blood samples, for the collection of these samples, and for the Coordinator's phlebotomy training to be tailored to the needs of this protocol.
   Funding Support: Dr. Trujillo's salary support at 2% effort has ended due to her resignation, effective 11/14/2014.

8. Name: Project   Joyce Sprafkin, PhD
   Role: Co-Investigator
   Person months worked: None
   Contribution to Project: Clinician. Dr. Sprafkin retired, effective April 2015.

9. Name: Project Role: Rebecca Weber,
   Contribution to Project: BA Coordinator
                                  Position termed 9-30-16

10.
10

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Kenneth D. Gadow, PhD
No change.

Ramin Parsey, MD, PhD
ACTIVE SUPPORT:
Advancing Personalized Antidepressant Treatment Using PETIMRI; NIMH; PI: DeLorenzo. R01
MH104512; 5/1/15- 4/30/19; Goals/Aims: To predict response to antidepressant treatment and
develop non-invasive techniques for PET imaging; Role: Co-I. CM:.24. Agency Contracting/Grants
Officer: Dr. Judith M. Rumsey. *This project has no financial or substantive overlap with AR130397.*
No Change.

Lithium's Molecular Mechanism of Action and the Pathology of Bipolar Disorders; NIMH. 1 R01
MH090276-01A1; 06/01/12-05/31/16; Goals/Aims: This project will utilize MRI and PET imaging
techniques to investigate the molecular mechanisms of lithium in a bipolar patient population
compared to healthy controls. This work will further develop our understanding of the pathology of
bipolar, and will contribute to our understanding of personal diagnosis and treatment. Role: PI. CM:4.
This project has no financial or substantive overlap with AR130397. No change.

PREVIOUS SUPPORT:
Characterizing Placebo Response; NIH; PI: Petkova. 1 R01 MH99003-01; 12/01/13- 11/30/15;
Goals/Aims: Clinical expertise will be provided to guide methodology development, interpret results,
and real-data validation of project's models. Role: Co-I. CM:.54. *This project has no financial or
substantive overlap with AR130397.*
Now complete support, active at last submission.

*Understanding the Molecular Mechanism of Action of Electroconvulsive Therapy in vivo Using
Positron Emission Tomography;* Brain & Behavior Research Foundation. 08/01/12- 07/31/16;
Goals/Aims: This study will use positron emission tomography to provide data essential for the
understanding of the role of the 5-HT1A receptor in major depressive disorder and specifically
electroconvulsive therapy's antidepressant mechanism of action. By understanding the
neurochemical mechanisms involved not only in the pathophysiology of major depressive disorder
but also the therapeutic action of ECT, significantly improved therapies can be developed. Role: PI.
CM:.24. *This project has no financial or substantive overlap with AR130397.*
Now complete support, active at last submission.

*Understanding the Mechanism of Action of Lithium and the Pathophysiology of Bipolar Disorder with
Molecular Imaging of the Serotonin System;* The DANA Foundation. 08/01/13- 07/30/13;
Goals/Aims: Examination of the effects of lithium of the serotonin transporter and 1A receptor; Role:
PI. CM:O. *This project has no financial or substantive overlap with AR130397.*
No change.

Biosignatures of Treatment Remission in Major Depression; NIMH; PI's: Weissman, Parsey, McGrath. 5U01 MH092250-04; 07/01/10- 06/30/16; Goals/Aims: This multi-site study will compare a serotonin selective reuptake inhibitor and placebo and assess a comprehensive array of clinical and biological moderators and mediators of outcome. Using innovative statistical approaches, the identified moderators and mediators will then be used to develop a differential depression treatment response index as a first step to developing personalized medication treatment of major depression disorder. Role: Co-PI. CM:.6. *This project has no financial or substantive overlap with AR130397.*
Now complete support, active at last submission.

Christine Delorenzo, PhD
ACTIVE SUPPORT:
Advancing Personalized Antidepressant Treatment Using PETIMRI; NIMH. R01MH104512; 5/1/15- 4/30/19; Goals/Aims: To predict response to antidepressant treatment and develop non-invasive techniques for PET imaging; Role: PI. 25o/o effort. Agency Contracting/Grants Officer: Dr. Judith M. Rumsey. *This project* has *no financial or substantive overlap with AR130397.*
No change.

Uncovering an Image-Based Biomarker of Depression; Stony Brook University. Fusion Seed Grant; 8/2015 – 6/2017; Goals/Aims: The goal of this grant is to develop an image-based biomarker of depression; Role: PI(no salary support). Agency Contracting/Grants Officer: Dr. Una M Obeid. *This project has no financial or substantive overlap with AR130397.*
No change.

Prediction of Antidepressant Treatment Response Using Magnetic Resonance Imaging (MRI); Dana Foundation. David Mahoney Neuroimaging Grant; 10/2015- 9/2018; Goals/Aims: To develop a high resolution diffusion imaging sequence to assess the health of white matter tracts prior to antidepressant treatment for the purposes of prediction; Role: PI(no salary support). Agency Contracting/Grants Officer: Kevin Aguirre. *This project* has *no financial or substantive overlap with AR130397.*
No change.

Personality Development and Vulnerability to First-Episode Depression; NIMH; Supplement to R01MH093479; 2014- 2017; Goals/Aims: In this project, we examine personality development, alongside other vulnerabilities, as a risk factor for first onset of depression. These vulnerabilities are related to structural and functional neuroimaging; Role: Co-I. 20o/o effort year 2. Agency Contracting/Grants Officer: Dr. Mercedes Rubio. *This project has no financial or substantive overlap with AR130397.*
No change.

PREVIOUS SUPPORT:
Cognitive Impairment in MS Linked to Structural and Functional Connectivity; Department of Defense; PI Dr. Lauren Krupp. MS130103; 2014- 2016; Goals/Aims: To use brain imaging to understand how the MS disease process causes cognitive impairment; Role: Co-I. 16% effort. Agency Contracting/Grants Officer: Peggi Lesnow. *This study involves many of the* same *types of imaging* as *the current proposal. However it* is *significantly different in that it* is *focused only on Multiple Sclerosis.*
Now completed support, active at last submission.

Characterization of a New Metabotropic Glutamate Receptor Subtype 5 PET Ligand; NIMH. 5K01MH091354-01; 5/1/11 – 4/30/15; Goals/Aims: To characterize the PET ligand [^{11}C]ABP688 for use in studies of depression and other mood disorders; Role: PI. 75°/o effort. Agency Contracting/Grants Officer: Dr. Christine Wise Clarkson. *This project* has *no financial or substantive overlap with AR130397.*
Now completed support, active at last submission.

Uncovering Biomarkers of Major Depressive Disorder Using MultimodalImaging; Irving Institute for Clinical and Translational Research Grant, Columbia University; 03/01/12 – 2/28/14; Goals/Aims: To

combine several imaging modalities, using advanced machine learning an statistical classification techniques that have been successful in integrating large amounts of information in other fields; Role: PI. Agency Contracting/Grants Officer: Michelle A. McClave. *This study involved many of the same types of imaging as the current proposal. However it was significantly different in that (1) It is focused only on depression (and not autism), (2) The imaging did not involve the highest resolution options or the simultaneous PETIMRI scanner, and (3) it was focused on methodology.*
No change.

Fronto-striatal circuitry in Parkinson's Disease; Hartman Foundation; PI Hoi-Chung Leung; 2013 – 2014; Goals/Aims: To develop neuroimaging experiments to examine functional and anatomical connectivity changes in patients in early stages of Parkinson's Disease; Role: Co-I. 2o/o effort. Agency Contracting/Grants Officer: Catherine Costanzo. *This project has no financial or substantive overlap with AR130397.*
No change.

Recruitment of Women in Biomedical Engineering (BME) through Mentored Internships in Neuroimaging; Presidential Mini-Grants for Departmental Diversity Initiative; 9/1/2013-06/30/2014; Goals/Aims: This funding is used to establish a pilot program providing medical imaging internships to undergraduate women throughout the academic year. Through guided research in state-of-the-art biomedical engineering (neuroimaging) techniques within a supportive and encouraging community, this highly technical and multidisciplinary field will be both accessible and enjoyable to participants. This will encourage women to major in engineering disciplines; Role: PI. Agency Contracting/Grants Officer: Barbara Doran-Lubitz. *This project has no financial or substantive overlap with AR130397.*
No change.

Matthew Lerner, PhD
ACTIVE SUPPORT:
Electrophysiological Correlates of Social-Emotional Learning in ASD Brain & Behavior Research Foundation (NARSAD); 01/15/17 – 01/14/19; Aims: 1) To examine differences in target EEG/ERP components and corresponding SELweb performance in a group of well-characterized youth with and without ASD. 2) To assess differences in the pattern of relations between these ERP components and their corresponding behaviors, and among these components themselves.; Role: PI. CM:1. *This project has no financial or substantive overlap with AR130397.*
Active support.

Optimizing Prediction of Social Deficits in Autism Spectrum Disorders; NIMH. 1 R 0 1 M H 1 1 0 5 8 5 - 0 ; 07/18/16 – 07/17/21; Aims: 1) To assess relations of intra-individual variables to "real world" outcomes in ASD . 2) Derive optimal combinations of intra-individual predictors contributing to social deficits in youth with ASD. 3) Specify sub-groups of participants based on shared patterns of social variables.; Role: PI. CM:19.2. *This project has no financial or substantive overlap with AR130397.*
Active support.

A Web-Based Tool to Assess Social Cognition in ASD; Simons Foundation. Explorer Award; 11/2015 -11/2016; Aims: 1) To evaluate the internal consistency of SELweb module scores. 2) To assess criterion validity of SELweb in comparison with existing social cognitive measures. 3) To evaluate SELweb performance in comparison to established normative data from general education youth; Role: PI. CM:1.0. *This project has no financial or substantive overlap with AR130397.*
Active support.

Effects of Active Emotion Identification; Alan Aida Fund for Communication. 05/2015 – 12/2016; Aims: 1) To assess whether AEI relates to specific psychophysiological mechanisms of social perception and cognition. 2) To determine if engagement in AEI relates to sustained changes social perception, cognition, and behavior across levels of analysis. 3) To ascertain whether effects on social perception, cognition, and behavior are evident in a "high need" population of young adults with ASD; Role: PI. CM:1.0. *This project has no financial or substantive overlap with AR130397.*
Active support.

Theater in School to Promote Youth with ASD - Pilot Study; Arts Connection. 10/2015 – 06/2017; Aims: 1) To identify and isolate elements of a school-based theater arts program (STAARS) thought to be related to social and academic outcomes in the special population of children with ASD by consulting stakeholders and observing students. 2) To determine whether the elements identified relate to changes in children's social, language, planning and attention skills, and creativity; Role: Co-Pl. CM:1.5. This project has no financial or substantive overlap with AR130397.
Active support.

Electrophysiological Effects of Social Performance-based Intervention for Autism Spectrum Disorder: A Randomized Controlled Trial; Stony Brook University, Department of Psychiatry. Pilot Grants Program; 07/2015- 07/2016; Aims: 1) Does SDARI affect neural mechanisms of social perception and cognition? 2) Do baseline characteristics predict response to SDARI?; Role: Pl. CM:1.0. *This project has no financial or substantive overlap with AR130397.*
Active support.

Cognitive Consequences of Emotion; National Science Foundation; PI: Gerald Clore, PhD, University of Virginia. 1252079; 2013- 2016; Aims: 1) To understand effects of emotional states on perception, memory, and creativity. 2) To assess the affect-as-information hypothesis on judgments in individuals with and without a predisposition towards a local processing focus; Role: Co-l. CM:.25. *This project has no financial or substantive overlap with AR130397.*
No change.

PREVIOUS SUPPORT:
Improving Effectiveness of Behavior Management Strategies at Maryhaven; Maryhaven Center of Hope. 8/15/15- 12/15/16; Goal/Aims: To identify factors associated with increased IISCIP-R gradienf' and injuries employing a comprehensive dataset obtained at Maryhaven during the 2014 calendar year; Role: Pl. CM:.28. *This project has no financial or substantive overlap with AR130397.*
Now completed support, active at last submission.

Consortium on Autism & Sign Language; American Academy of Arts & Sciences. Exploratory Fund; 03/2015- 03/2016; Goals/Aims: We will hold a two-day symposium of Academy Fellows as well as nationally known researchers in two areas: sign language linguistics and the study of social communication among individuals with autism spectrum disorders (ASD). The symposium will be held at the Norton Woods Conference Center at the House of the Academy in Cambridge in mid-December 2015; Role: Co-Pl. CM:1.0. *This project has no financial or substantive overlap with AR130397.*
Now completed support, active at last submission.

Consortium on Autism & Sign Language; Nancy Lurie Marks Family Foundation. Sponsored Symposium Grant; 2014- 2015; Goals/Aims: Same as American Academy of Arts & Sciences, above; Role: Pl. CM:.6. *This project has no financial or substantive overlap with AR130397.* Now completed support, active at last submission.

Patricia Whitaker-Azmitia, PhD
No change.

Jie Yang, PhD
ACTIVE SUPPORT:
ME/CFS: Activity Patterns and Autonomic Dysfunction. 1R01NR016227-01 Friedberg (PI) 04/01/2016-03/31/2020. Goal:1) To assess the relation between non-improvement and prospectively assessed activity patterns and life events; 2) To assess the relation between improvement and prospectively assessed activity patterns and life events.; 3) To assess the relation between activity patterns and symptoms. *This project has no financial or substantive overlap with AR130397.* Active support not yet pending at last submission.

Advancing Virtual Colonoscopy for Early Cancer Screening. 1R01CA206171-01A1 Liang (PI) 06/03/2016-05/31/2021. Goal: 1*)* To develop and evaluate adaptive image reconstruction and image processing algorithms to retain image textures for polyp detection and characterization with as low as achievable CT radiation;2) To explore and evaluate texture features as imaging biomarkers to detect polyps and characterize polyp Subtypes. *This project has no financial or substantive overlap with AR130397.* Active support not yet pending at last submission.

P13K Signaling and Channelopathies in the Heart. 1R01DK108989 Lin (PI) 07/01/2016-06/30/2020. Goal: to examine how PI3K/Akt regulates the function of Nav1.5 and HCN2 channels and investigates the effects of insulin resistance on I_{NaP} and I_h. *This project has no financial or substantive overlap with AR130397.* Active support not yet pending at last submission.

Targeted Approach for Prevention and Therapy of Colorectal Cancer. 1R01CA17211301A1 Yang(PI) 07/01/2013-06/30/2017. Goal: To evaluate a novel compound which potently and selectively inhibits KLF5 as a therapeutic candidate for colorectal cancer. Role: Co-l. 1.5°/o effort. *This project has no financial or substantive overlap with AR130397.*
No change.

Sphingolipids in Cancer Therapy and Biology. 2P01CA09713211A1 Hannun(PI) 09/02/2014-08/30/2019. Goal: To investigate the role of sphingolipids in tumor initiation and differentiation, growth and death of tumor cells, tumor cell invasiveness and metastasis and tumor senescence. Role: Lead Biostatistician. 20°/o effort. *This project has no financial or substantive overlap with AR130397.*
No change.

PREVIOUS SUPPORT:
Plasticity-based, adaptive, computerized cognitive remediation treatment (PACR) for adults with Multiple Sclerosis (MS). RG 4808A8/1 Krupp (PI) 04/03/2013-03/31/2016. Goals: 1) To evaluate the effect of plasticity-based, adaptive, computerized cognitive remediation ("PACR") on generalized cognitive and functional performance, 2) To identify specific predictors of response to guide future use; Role: Co-l. 4.5°/o effort for year 1-2; 9% effort for year 3. *This project has no financial or substantive overlap with AR130397.*
Now completed support, active at last submission.

Cognitive Impairment in MS Linked to Structural and Functional Connectivity Effect. W81XWH1410248 Krupp (PI) 9/29/2014-9/28/2016. Goals: 1) To measure cognitive Intra- Individual Variability (IIV) in multiple Scerloris MS and healthy control participants to serve as an index of cognitive impairment and measure structural, functional and metabolic imaging markers to serve as indices of MS disease pathology, 2) To link these measures to identify the biological basis of cognitive impairment in MS. Role: Co-l. 10°/o effort. *This project has no financial or substantive overlap with AR130397.*
Active support not yet pending at last submission.

A Pilot Study of Regional Cerebral Oxygen Saturation (rS02) Monitoring in Predicting Neurological and Survival Outcomes. 13CRP17440000 Parnia (PI) 07/01/2013-06/30/2015. Goals: To measure the level of rS02 achieved during CPR and in the first 24 hours of the post resuscitation period in cardiac arrest patients to investigate the level of rS02 and optimal read out signal that is associated with survival, neurological and functional outcomes at discharge, and 30 days following cardiac arrest. Role: Co-l. 1°/o effort. *This project has no financial or substantive overlap with AR130397.*
No change.

Screening Lung Cancer by Ultra Low-Dose Computed Tomography. 5R01CA143111 Liang (PI) 07/01/2010-04/30/2015. Goal: To reduce the X-ray exposure risk by lowering the mAs value as low as achievable, while retaining the image quality suitable to the clinical task. Role: Co-l. 3.2o/o effort. *This project has no financial or substantive overlap with AR130397.*
No change.

Developing Virtual Colonoscopy for Cancer Screening. 5R01CA082402 Liang (PI) 04/01/2001-05/31/2014. Goal: To develop computed tomography colonography (CTC) or CT-based virtual colonoscopy (VC) toward a screening modality by using (1) as low as achievable low-dose CT scan, (2) less-stressful bowel preparation (BP), e.g., minimal laxative and/or cathartic-free BP, and (3) integration of computer-aided detection (CAD) and three-dimensional (3D) endoscopic views for polyp detection. Role: Co-I. 1.8o/o effort. *This project has no financial or substantive overlap with AR130397* No change.

What other organizations were involved as partners?   Nothing to Report.

8. SPECIAL REPORTING REQUIREMENTS: None.

9. APPENDICES:

Revised SOW

YEAR 1

Aim #1: Obtain Institution Review Board (IRB) approval for DOD application
    1a. Task: Obtain IRS approval Responsible personnel: Dr. Gadow
       Milestone: IRB approval secured
       Timeline: Prior to award Week 0 (9/30/2014)

    1b. Task: Submit IRB DOD amendment to existing IRB approval
       Responsible personnel: Dr. Gadow
       Milestone: Complete and submit IRB amendment
       Timeline: Weeks 1-4 (10/7/2014- 10/28/2014)

    1c. Task: Obtain IRS amendment approval
       Responsible personnel: Dr. Gadow
       Milestone: Complete and submit revised IRS forms
       Timeline: Weeks 4-6 (10/28/2014- 11/11/2014)

Aim #2: Prepare for subject recruitment
    2. Task: Prepare subject recruitment materials
       Responsible personnel: Dr. Gadow, Coordinator
       Milestones: Solicitation lists, advertisements
       Timeline: Weeks 6-11 (11/11/2014 -12/16/2014)

Aim # 3: Recruitment for Phase 1
    3a. Task: Recruitment of first block of 28 Phase 1 participants
       Responsible personnel: Dr. Gadow, Coordinator
       Milestone: Initiate participant solicitation
       Timeline: Weeks 12-52 (12/23/2014- 9/30/2015)

YEAR2

Aim # 3: Recruitment, data collection, and data processing for Phase 1
    3a. Task: Recruitment of first block of 10 Phase 1 participants
       Responsible personnel: Dr. Gadow, Coordinator
       Milestone: Continue participant solicitation
       Timeline: Weeks 1-34 (10/1/2015 – 6/1/2016)

    3b. Task: Collect psychosocial data
       Responsible personnel: Dr. Gadow, Coordinator
       Milestones: Administer diagnostic and psychosocial measures, collect blood samples
       Timeline: Weeks 34-52 (6/1/2016 – 9/30/2016)

    3c. Task: Record and enter diagnostic and psychosocial data
       Responsible personnel: Dr. Gadow, Coordinator
       Milestones: Score assessment measures and enter data for analyses
       Timeline: Weeks 34-52 (6/1/2016 – 9/30/2016)

    3d. Task: Collecting and storing Phase 1 immunologic data
       Responsible personnel: Dr. Gadow, Coordinator
       Milestones: Collect and properly store blood samples
       Timeline: Weeks 34-52 (6/1/2016 – 9/30/2016)

Aim # 4: Recruitment, data collection, and data processing for Phase 2
    4a. Task: Recruitment of first block of 3 Phase 2 participants

Responsible personnel: Dr. Gadow, Dr. DeLorenzo, Coordinator
Milestone: Initiate participant solicitation
Timeline: Weeks 39-52 (7/1/2015 – 9/30/2016)
4b. Task: Conduct fMRI
Responsible personnel: Dr. Gadow, Dr. DeLorenzo, Coordinator
Milestone: Conduct fMRIs
Timeline: Weeks 39-52 (7/1/2015 – 9/30/2016)
4c. Task: Storing and processing Phase 2 fMRI data
Responsible personnel: Dr. DeLorenzo
Milestones and timeline: Storing and initial processing fMRI data Weeks 39-52 (7/1/2015 – 9/30/2016)

YEAR 3 No-cost Extension

Aim #5: Repeat everything in Aim #4, recruit 45 participants for Phase 1 and 29 participants for Phase 2
    Timeline: Weeks 1-46 (10/1/2016 – 7/31/2017)

Aim #6: Analyze the data with regard to the stated hypotheses of the study
    6. Task: Conduct data analyses
    Responsible personnel: Dr. Yang, Dr. Gadow, Dr. DeLorenzo,
    Milestone: Data analyses will be conducted using SPSS
    Timeline: Weeks 46-52 (8/1/17 – 9/29/17)

Aim #7: Prepare abstracts, presentations, and manuscripts

    7. Responsible personnel: Dr. Gadow, Dr. Parsey, Dr. DeLorenzo, Dr. Yang, Dr. Whitaker-Azmitia
    Milestones: Submit proposals to present at national or international meetings and prepare for submission manuscripts to peer-reviewed journals
    Timeline: Weeks 46-52 (8/1/17 – 9/29/17)

	Year 2				Year 3			
Target Enrollment (per quarter)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Phase 1			4	1	13	13	13	6
Phase 2			0	1	9	9	9	2
Target Enrollment (cumulative)								
Phase 1			0	5	18	31	44	50
Phase 2			0	1	10	19	28	30

▾ Stony Brook Medicine

Department of Psychiatry

HSC, Level 10, Room 020
Stony Brook, NY 11794-8101

TEL: 631.444-3084
FAX: 631.444-1560

October 21, 2015

Dear Sir/Madam:

In the Spring of 2014, Dr. Gadow learned from Dr. Turban Canli, Ph.D., Director of the SCAN (Social, Cognitive, and Affective Neuroscience) Center at Stony Brook University (SBU), that the MRI scanner was to be updated (Prisma upgrade), and that the work was expected to be completed before the start of his study. However, by November 2014, the SCAN Center upgrade still had not been completed.

Because the quality of the scans from the upgraded scanner would be so superior to the current scans, it was recommended to Dr. Gadow that he wait before running any subjects until the upgrade was completed. Starting the scans before the upgrade was completed would also introduce a serious methodological confound (i.e., data from what would be two different scanners). This is particularly serious for a pilot study where sample size was small.

On January 21, 2015, Dr. Canli distributed an email indicating that SBU's Purchasing Office had finally approved and submitted the order for the new Prisma upgrade to the SCAN Center. He further indicated that there would be a site visit with various technical/construction workers in the next week or two. He further indicated, assuming no unpleasant surprises, that we had a tentative time frame of early to mid-April (2015) for delivery of the new system. Installation would take about 5-6 weeks, followed by a week or two of training. He expected the new system to be up-and-running and open for business by late May or early June, 2015.

On May 11, 2015, Dr. Canli distributed an email indicating that in the process of testing the building for the new scanner installation, it was discovered that there was water damage to the magnetic shield in the floor and ceiling. The source of the water leak was the roof of the SCAN Center. This would need to be corrected before the new magnet could be installed. Accordingly, the installing company, Universal Shielding, was now in the process of drawing up a quote, to be followed by the manufacturing of replacement shield panels. He indicated that, "At this time, I do not know when this process will be approved/completed, and therefore cannot tell you when the new scanner will become operational. My most optimistic guess is sometime in August [2015], definitely not before then." At this writing, the SCAN Center is still not functional and the next projected operational date is early next year (2016).

Anticipating the possibility of potential problems with the upgrade, I discussed with Dr. Gadow in December 2014 the possibility of using the Stony Brook University Hospital's (SBUH) dedicated research PET/MR to conduct his study. The one major stumbling block, however, was that the PET/MR was not equipped to do fMRI. In order to resolve this issue, it would be necessary to obtain administrative approval and funding to proceed to order the

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8

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equipment and have it installed and fully functional. By May 2015, the fMRI equipment for the PET/MR began to arrive and over the next several months it was installed and tested.

As the SCAN Center MRI is still not functional, I have personally arranged for Dr. Gadow to begin scanning his subjects on the SBUH's PET/MR. This will be done at no extra cost to him or his grant. In order to make up for the time he lost as a result of SCAN center equipment problems completely beyond his control, he may be asking for a no-cost extension in September 2016 to complete the study. As Director of PET Research, I will ensure that Dr. Gadow has the necessary resources to complete the study during a no-cost extension. As Chainnan of the Department of Psychiatry, I will make sure that he has the necessary financial support during a no-cost extension should this prove necessary. Importantly, there will be no added costs to the grant to use the SBUH's scanner.

Thank you.

Sincerely,
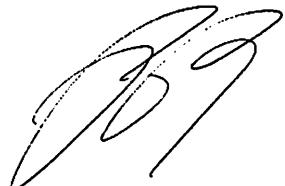
Ramin Parsey MD, PhD
Professor and Chair, Department of Psychiatry
Della Pietra Family Chair in Biomedical Imaging
Professor of Radiology
Director of PET Research
Co-Director, Neurosciences Institute
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The best ideas in medicine.

From: "Canli, Turhan" <Turhan.Canli@stonybrook.edu>
To: "Strey, Lilianne R." <Lilianne.Strey@stonybrook.edu>, "Gonzalez, Adam"
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<Ramin.Parsey@stonybrookmedicine.edu>, "Kotov, Roman"
<Roman.Kotov@stonybrookmedicine.edu>, "Canli, Turhan" <Turhan.Canli@stonybrook.edu>
Cc:
Date: Mon, 11 May 2015 19:39:39 +0000
Subject: Scanner upgrade update
Dear Pis,

in the process of testing the building for the new scanner installation, we discovered water damage to the
magnetic shield in the floor and ceiling. This will need to be replaced before the new magnet can be
installed. Accordingly, the installing company, Universal Shielding, is now in the process of drawing up a
quote, to be followed by the manufacturing of replacement shield panels. At this time, I do not know when
this process will be approved/completed, and therefore cannot tell you when the new scanner will become
operational. My most optimistic guess is some time in August, definitely not before then.
Turhan

Turhan Canli, Ph.D.
Associate Professor, Integrative Neuroscience in Psychology and Radiology
Director, *SCAN* (Social, Cognitive, and Affective Neuroscience) Center
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TEDx talk: http://youtu.be/1dD29XHp6CU